

DEC 31 2003

510(k) Summary

Imaging Therapeutics, Inc.

Knee Interpositional Mini-Repair System

510(k) Notification K033242

GENERAL INFORMATION

Manufacturer:

Imaging Therapeutics, Inc.
1720 Amphlett Blvd Suite 240
San Matco, CA 94402
Phone 650-286-4166
FAX 650-286-4160

Contact Person:

Lyndall Erb, PhD
Director, Regulatory/Clinical Affairs & Quality Assurance

Date Prepared:

October 3, 2003

DEVICE INFORMATION

Trade/Proprietary Name

Knee Interpositional Mini-Repair System (KIMRS) / TBD

Common/Classification Name

Hemi-knee prosthesis

21 CFR 888.3590 – Knee joint Unicondular Interpositional (hemi-knee) metallic resurfacing un-cemented prosthesis

Class II

Device Product Code: HSH

K033042
page 2 of 4

PREDICATE DEVICES

The Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System is substantially equivalent to FDA-approved predicate devices with regard to indications for use and technological characteristics. These predicate devices are:

Indications for Use	Technological Characteristics
<ul style="list-style-type: none">• Hayes Medical, Patient Specific Implant (PSI)-Femoral Component (K964395)• Biomet, Patient Matched Implants, Femoral Implants (K911802)• Techmedica, CAD/CAM Custom Hip (K911058)	<ul style="list-style-type: none">• Sulzer Orthopedics, Inc., (Centerpulse), Unicondylar Interpositional Spacer (K003269)• OTI Unicondular Interpositional Spacer System (K022779)• McKeever Hemiarthroplasty Prosthesis (Preamendment device)

INTENDED USE

The Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System (KIMRS) is intended for use in the osteoarthritic knee, where substantial amounts of articular cartilage have degenerated as a result of the disease, and in patients who are candidates for total and/or uni-compartmental arthroplasty procedures. The implant is indicated for the un-cemented treatment of the medial and/or lateral tibial articulating surfaces of the following:

Moderate degeneration of the medial or lateral compartment of the knee (grade II-IV chondromalacia) and minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the patellofemoral compartments.

The Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System is intended to be implanted in the knee as a non-fixated, intra-articular support with minimal to no movement of the device after implantation.

PRODUCT DESCRIPTION

Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System is a minimally invasive, bone preserving, approach for the treatment of the osteoarthritic knee. Developed from patient Magnetic Resonance (MR) scans a patient specific implant is designed.

The treatment allows for the placement of an un-cemented metallic device designed from the patient's natural cartilage and meniscal geometry that is implanted into the joint space either in the medial or lateral compartment above the affected tibial plateau. The femur then articulates against the smooth implant surface. The implant is manufactured from cobalt chromium molybdenum alloy.

k033242
page 3 of 4

SUBSTANTIAL EQUIVALENCE

Technological Characteristics

The technological characteristics of the Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System are identical to those of the cited predicate orthopedic devices. This device is equivalent in terms of design process, materials, production process, and equipment.

Indications for Use

Substantial equivalence is also supported for the Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System by the predicate devices previously cited and cleared in the treatment of osteoarthritic knees where total knee replacement is not warranted.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

To compare the properties of the ImaTx Knee Interpositional Mini-Repair System with that of the Centerpulse Unispacer, both implants were inserted into the same cadaveric knee and examined under fluoroscopy. The test was performed on two knee specimens.

In the lateral view, anterior and posterior landmarks were chosen on the tibial plateau. The maximum motion of the anterior edge of the implant with respect to the anterior landmark and of the posterior edge of the implant with respect to the posterior landmark was recorded over the range from 0° (full extension) to 150° of flexion. Similarly, the maximum medio-lateral excursion of both implants was measured in the AP views. The results are listed in the table below.

Table 1. Maximum excursion of KIMRS compared to Unispacer

Cadaver Knee 1	ImaTx KIMRS (in mm)	Unispacer (in mm)
Implant Length	42	46
Implant Width	25	29
Anterior Excursion (Lateral view)	4.5	3.1
Posterior Excursion (Lateral view)	4.8	6.0
Medial-Lateral Excursion (Anterior-Posterior View)	1.2	2.8
Cadaver Knee 2		
Implant Length	42	50
Implant Width	25	31
Anterior Excursion (Lateral view)	3.6	4.0
Posterior Excursion (Lateral view)	2.9	4.5
Medial-Lateral Excursion (Anterior-Posterior View)	0.3	1.9

The ImaTx Knee Interpositional Mini-Repair System performed comparably to the Unispacer implant. On the lateral view, the values for anteroposterior translation are similar for both implants. Of note, the anterior and the posterior values should be similar or the same if the implant exhibits only translational movement. Remarkably, there is a significant difference in anterior and posterior maxima seen with the Unispacer in knee #1. This appears to be the result of implant rotation in addition to translation. Thus, the data in knee #1 indicate that the Unispacer rotates in addition to anteroposterior translation.

On the AP view, the ImaTx Knee Interpositional Mini-Repair System demonstrated no significant translation medially. The Unispacer, demonstrated considerably more movement medially.

SUMMARY

Based on the similarities in design, materials, function, and intended use, the Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. In addition, the Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System raises no new safety or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 31 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lyndall Erb, Ph.D.
Director Regulatory/Clinical Affairs & Quality Assurance
Imaging Therapeutics, Inc.
1720 South Amphlett Boulevard, Suite 240
San Mateo, California 94402

Re: K033242

Trade/Device Name:s Knee Interpositional Mini-Repair System (KIMRS)

Regulation Numbers: 21 CFR 888.3590

Regulation Names: Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis

Regulatory Class: II

Product Codes: HSH

Dated: October 3, 2003

Received: October 7, 2003

Dear Dr. Erb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033242

Imaging Therapeutics, Inc.

Knee Interpositional Mini-Repair System

510(k) Premarket Notification

STATEMENT OF INDICATIONS FOR USE

The Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System (KIMRS) is intended for use in the osteoarthritic knee, where substantial amounts of articular cartilage have degenerated as a result of the disease, and in patients who are candidates for total and/or unicompartmental arthroplasty procedures. The implant is indicated for the un-cemented treatment of the medial and/or lateral tibial articulating surfaces of the following:

Moderate degeneration of the medial or lateral compartment of the knee (grade II-IV chondromalacia) and minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the patellofemoral compartments.

The Imaging Therapeutics, Inc. Knee Interpositional Mini-Repair System is intended to be implanted in the knee as a non-fixed, intra-articular support with minimal to no movement of the device after implantation.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033242